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Applicant(s): A.F. Carter

Docket No.

ARK-908US

Patent No.

4,600,706

Issue Date

July 15, 1986

Examiner

Johnnie R. Brown

Group Art Unit

Unknown

Invention: ANTI-FUNGAL FEED COMPOSITIONS CONTAINING NATAMYCIN

MAY 13 2004

PATENT &amp; TRADEMARK OFFICE

I hereby certify that the following correspondence:

Transmittal Form

Fee Transmittal Form

Application for Patent Term Extension

Exhibits 1 - 5

(Identify type of correspondence)

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APP 1

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# TRANSMITTAL FORM

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Total Number of Pages in This Submission

Patent Number.	4,600,706
Issue Date	July 15, 1986
First Named Inventor	A.F. Carter
Art Unit	Unknown
Examiner Name	Johnnie R. Brown
Attorney Docket No.	ARK-908US

## ENCLOSURES (Check all that apply)

- |   |  |   |
|---|--|---|
| <input checked="" type="checkbox"/> Fee Transmittal Form<br><input type="checkbox"/> Fee Attached<br><input type="checkbox"/> Amendment/Reply<br><input type="checkbox"/> After Final<br><input type="checkbox"/> Affidavits/Declaration(s)<br><input type="checkbox"/> Extension of Time Request<br><input type="checkbox"/> Express Abandonment Request<br><input type="checkbox"/> Information Disclosure Statement<br><input type="checkbox"/> Certified Copy of Priority Document(s)<br><input type="checkbox"/> Response to Missing Parts/<br>Incomplete Application<br><input type="checkbox"/> Response to Missing Parts under<br>37 CFR 1.52 or 1.53 | <input type="checkbox"/> Drawing(s)<br><input type="checkbox"/> Licensing-related Papers<br><input type="checkbox"/> Petition<br><input type="checkbox"/> Petition to Convert to a<br>Provisional Application<br><input type="checkbox"/> Power of Attorney, Revocation,<br>Change of Correspondence<br>Address<br><input type="checkbox"/> Terminal Disclaimer<br><input type="checkbox"/> Request for Refund<br><input type="checkbox"/> CD, Number of CD(s) _____ | <input type="checkbox"/> After Allowance Communication<br>to Group<br><input type="checkbox"/> Appeal Communication to Board<br>of Appeals and Interferences<br><input type="checkbox"/> Appeal Communication to Group<br>(Appeal Notice, Brief, Reply<br>Brief)<br><input type="checkbox"/> Proprietary Information<br><input type="checkbox"/> Status Letter<br><input checked="" type="checkbox"/> Other Enclosure(s) (please<br>identify below):<br>Application for Patent Term Extension |
|---|--|---|

Remarks:

## SIGNATURE OF APPLICANT, ATTORNEY OR AGENT

Firm or Individual	Basil S. Krikellis	Registration No. (Attorney/Agent)	41,129
Signature			
Date	May 13, 2004		

## CERTIFICATE OF TRANSMISSION / MAILING

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Name (Print/Type)	Regina Poletti		
Signature		Date	May 13, 2004

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, ALEXANDRIA, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



Patent Term Ext.  
U.S. Pat. No. 4,600,706  
Page 1 of 12

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Patent No: 4,600,706  
Applicant: A.F. Carter  
Issued: Jul 15, 1986  
Title: ANTI-FUNGAL FEED COMPOSITIONS CONTAINING NATAMYCIN

Mail Stop Patent Ext.  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**RE:** Application for Patent Term Extension  
Arkion Life Sciences LLC  
U.S. Patent No. 4,600,706

Sir:

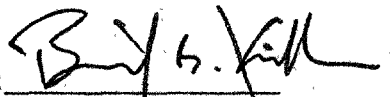
Transmitted herewith is the Application for Patent Term Extension under 35 U.S.C. § 156(d) with regard to U.S. Patent No. 4,600,706.

Please charge Deposit Account No. 50-0929 in the amount of \$1,120.00. We also ask that you please charge Deposit Account No. 50-0929 for any other fees associated with this request.

U.S. Patent No. 4,600,706 (the "Patent") was assigned from Ducoa L.P. to Arkion Life Sciences LLC (herein referred to as "Applicants") on July 30, 2001 (Reel/Frame No. 012463/0992).

Please note, this application is submitted in triplicate as per 37 CFR § 1.740(b).

Respectfully Submitted

By: 

Basil S. Krikellis  
Reg. No. 41,129  
Christian M. Bauer  
Reg. No. 51,443  
Attorneys for Applicants

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Patent No: 4,600,706  
Applicant: A.F. Carter  
Issued: Jul 15, 1986  
Title: ANTI-FUNGAL FEED COMPOSITIONS CONTAINING NATAMYCIN

**APPLICATION FOR INTERIM PATENT TERM  
EXTENSION UNDER 35 U.S.C. § 156(d)(5)**

Commissioner for Patents  
Mail Stop Patent Ext.  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This application for a patent term extension of U.S. Patent No. 4,600,706, which satisfies the conditions for extension of patent term under 37 C.F.R. § 1.720, and is filed under 35 U.S.C. § 156(d), complies with the requirements of 37 C.F.R. § 1.720 and includes all of the information required for a complete application under 37 C.F.R. § 1.741. For the convenience of the Patent and Trademark Office, the information contained in this application is presented following the format of 37 C.F.R. § 1.740.

U.S. Patent No. 4,600,706 was assigned from Ducoa L.P. to Arkion Life Sciences LLC (herein referred to as "Applicants") on July 30, 2001 (Reel/Frame No. 012463/0992).

Pursuant to 35 U.S.C. § 156 (d)(1), this application for patent term extension is submitted within the sixty (60) day period beginning on the date the product received permission to market from the FDA and was published in the Federal Register, namely, Tuesday April 13, 2004.

This application is submitted in triplicate as required under 37 C.F.R. § 1.740(b).

**In accordance with 37 C.F.R. § 1.740(a)**

(1) The product that underwent regulatory review is NSURE®. NSURE® is a 1.0 lb (454 g) premix composition of calcium carbonate (433 g), lactose (10 g) and natamycin (11 g), which is the additive. The additive is a stereoisomer of 22~[(3-amino-3,6,dideoxy-B-D-mannopyranosyl)oxy]-1,3,46-trihydroxy-12-methyl-10-oxo-6,11,28-trioxatricyclo[22.3.2.0<sup>5,7</sup>]octacos-8,14,16,18,20-pentaene-25-carboxylic acid with the empirical formula C<sub>33</sub>H<sub>47</sub>NO<sub>13</sub>.

(2) The feed additive was subject to review under the Section 409(b)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 348(a)).

(3) The NSURE® product received commercial approval on Tuesday, April 13, 2004 as published in the Federal Register Vol. 69, No. 71.

(4) The NSURE® product is not a drug product.

(5) This application is being submitted within the sixty-day period permitted under 37 C.F.R. § 1.720(f) and the last day on which a petition could be submitted is June 14, 2004. (June 12 is a Saturday).

(6) The complete identification of the patent for which interim extension is being sought:

Name of Inventor: A.F. Carter  
Patent Number: 4,600,706  
Date of Issue: July 15, 1986  
Date of Expiration: November 17, 2003 (determined by 35 U.S.C. § 154(c))

(7) A copy U.S. Patent No. 4,600,706 for which the patent term extension is being sought, including the entire specification, claims and drawings, is attached as **Exhibit 1**.

(8) U.S. Patent No. 4,600,706 is subject to a terminal disclaimer attached as **Exhibit 2**. No certificate of correction has been issued with regard to U.S. Patent No. 4,600,706. Receipt of maintenance fee payments made in full are attached as **Exhibit 3**. No reexamination certificate has been requested nor issued for U.S. Patent No. 4,600,706.

(9) U.S. Patent No. 4,600,706 claims a method for using the product set forth in paragraph (1) above. Claims 1-6 recite a method for improving animal feed by blending an amount of natamycin, the feed additive contained in the approved product, into animal feed. Specifically, claims 1, 2 and 5 claim the approved use for the approved product.

As stated in (1) above, the product, NSURE® containing natamycin, was approved for use as a feed additive. NSURE® is a 1.0 lbs (454 g) premix composed of calcium carbonate (433 g), lactose (10 g) and natamycin (11 g) for retarding growth of *Aspergillus Parasiticus* in broiler chicken feeds. Approved use includes

blending the NSURE® 1.0 lbs premix into 1.0 ton of animal feed. The weight percent of natamycin in the blended ton of animal feed is calculated to be 0.00011 weight percent. See Col. 7, lines 53-55 of U.S. Patent No. 4,600,706 for conversion calculations.

Claim 1 recites:

1. A method for improving animal feed which contains moisture to prevent or inhibit the onset of and reduce fungal or mold growth in the feed prior to consumption by an animal to thereby prevent or inhibit mycotoxicoses in the animal, which comprises blending about 0.000055 to 0.011 weight percent of natamycin into the animal feed.

According to the conversion contained in U.S. Patent 4,600,706 at Col. 7, lines 53-55, the weight percent of natamycin is calculated to be 0.00011, which is within the range of 0.000055 to 0.011 weight percent as recited by claim 1.

Further, if the preamble were construed to give meaning to the claim, particularly, the language of "prevent[ing] or inhibit[ing] the onset of and reduce[ing] fungal or mold growth in the feed," the approved product would still be within the scope of claim 1 because the approved use of the approved product was to retard or inhibit growth of *Aspergillus Parasiticus*, a fungi known to grow on feed.

Claim 2 recites:

2. A method according to claim 1 wherein the natamycin is dry blended into the animal feed in admixture with an inert carrier.

The approved use of the NSURE® product is within the scope of claim 2. The use of the NSURE® product is a premix composed of calcium carbonate, lactose and natamycin. Because claim 2 depends from claim 1, the limitations of the weight percent of natamycin are met. Further, with regard to the limitation in claim 2 of an inert carrier, the NSURE® premix contains the inert carrier of calcium carbonate which is blended with natamycin in the premix. Therefore, when appropriately used, the approved product, NSURE®, falls within the scope of claim 2.

Claim 5 recites:

5. A method according to claim 2 wherein the inert carrier is one or more members selected from the group consisting of rice hulls, calcium carbonate, soybean mill feed, and corn fractions.

The approved use of the NSURE® product is within the scope of claim 5. Claim 5 specifically recites that the inert carrier of claim 2 can be selected from a group of inert carriers which includes calcium carbonate. The approved, NSURE® product contains calcium carbonate. Therefore the approved use of the approved product falls within the scope of claim 5.

Claims 3 and 6 also depend directly or eventually from claim 1 which, as discussed above, covers the approved use of the approved product. In particular, claim 3 further defines the method of improving animal feed by blending natamycin with an animal feed having a specific moisture content. Claim 6 further defines the method of improving animal feed by blending natamycin with animal feed having specific properties including a specific grain size. Because by their very nature dependent claims contain each and every limitation of the intermediary and independent claim from which they depend, the scope of claims 3 and 6 are within the approved of the NSURE® product. Therefore, Applicants submit that the approved use of the of the NSURE® product falls within the scope of claims 3 and 6.

(10) The relevant dates and information pursuant to 35 U.S.C. § 156(g) enabling the Secretary of Health and Human Services or the Secretary of Agriculture to determine the applicable regulatory review period are as follows:

(iv) For a patent claiming a food or color additive:

(A) Investigational Food Additive Petition (IFAP 6454) to use the antifungal substance natamycin at the rate of 10 grams per ton of poultry feed was filed on **May 1, 1989**. The FDA acknowledged receipt of the petition on May, 8, 1989.

(B) Applicants filed a food additive petition (FAP 2234; Docket No. 95F-0221) on **June 30, 1995**. The petition was published in the Federal Register on September 20, 1995 (60 FR 48715), announcing that DuCoa L.P., now Applicants Arkion Life Sciences, proposed the use of natamycin as a mold retardant in broiler chicken feed. The FDA reviewed FAP 2234 and issued a response on June 26, 1996, requesting additional, extensive studies. After completion of the additional requested studies, an amendment to FAP 2234 was filed on July 31, 2001.

(C) The amended Food Additive Petition (FAP 2234) for NSURE® premix containing natamycin, was approved on Tuesday, April 13, 2004 as published in Vol. 69, No. 71 of the Federal Register.



(11) A brief description of the major activities undertaken by applicants during the applicable regulatory review periods are presented in chronological order and attached as **Exhibit 4**. Also included as **Exhibit 5** are the major communications between applicants and pertinent FDA officials.

(12) Applicants are of the opinion that U.S. Patent No. 4,600,706 is eligible for extension because it satisfies all of the requirements for such extension under 35 USC 156 as follows:

35 U.S.C. § 156 (a)

U.S. Patent No. 4,600,706 claims a method of using a product.

35 U.S.C. § 156 (a)(1)

The term of U.S. Patent No. 4,600,706 has not expired before submission of this application as an application for interim extension was filed in accordance with 35 U.S.C. § 1.56(d) on November 3, 2003.

35 U.S.C. § 156 (a)(2)

The term of U.S. Patent No. 4,600,706 has never been previously extended, except for interim extension pursuant to 37 C.F.R. § 1.790.

35 U.S.C. § 156 (a)(3)

This application for extension is being submitted by the agent of record in accordance with the requirements of 35 U.S.C. § 156(d)(1)-(4) and the Rules of the U.S. Patent and Trademark Office.

35 U.S.C. § 156 (a)(4)

The Product NSURE® has been subject to a regulatory review period before its commercial marketing or use.

35 U.S.C. § 156 (a)(5)(A)

Tuesday April 13, 2004, was the first permitted commercial marketing use of NSURE® after regulatory review under the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 348(a)), which such regulatory review period occurred.

35 U.S.C. § 156 (a)(5)(C)(i) and (ii)

The approved product, NSURE®, is (i) not covered by the claims in any other patent which has been extended and (ii) was not extended on the basis of the regulatory review period for use in non-food-producing animals.

Provisions for calculation of the Regulatory Review Period are set forth in both 35 U.S.C. § 156 and 37 CFR §1.776 as follows:

(A) Calculation of Regulatory Review Period under 35 U.S.C. § 156 (g)(2)(B)

35 U.S.C. § 156(g)(2)(B)(i)

May 1, 1989, was the date on which the a major health or environmental effects test on the additive was initiated. July 30, 1995, was the date Food Additive Petition 2234 was initially submitted with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product. This time period spanned **2250 days** or **6.2 years**.

35 U.S.C. § 156(g)(2)(B)(ii)

July 30, 1995, was the date Food Additive Petition (FAP) 2234 was initially submitted with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product. NSURE®, the subject product of FAP 2234, received market approval as published in the Federal Register on Tuesday April 13, 2003. This time period spans **3181 days** or **8.7 years**.

The sum of (g)(2)(B)(i) and (g)(2)(B)(ii) is **5431 days** or **14.9 years**, the Regulatory Review Period.

(B) Calculation of the Patent Term Extension under 37 CFR §1.776.  
Calculation of the Patent Term Extension is further calculated as provided for in 37 CFR §1.776.

37 CFR § 1.776(d)(1)

Subtracted from the Regulatory Review Period calculated in 35 U.S.C. § 156 (g)(2)(B), was the sum of d(1)(i) through (d)(1)(iii) calculated below. The result was **4139 days** or **11.3 years**. [=5431-0-334-958]

37 CFR § 1.776(d)(1)(i)

The were **zero (0)** days of the regulatory review period that occurred before the date on which the patent issued 15 July 1986.

37 CFR § 1.776(d)(1)(ii)

The time period that applicant did not act with due diligence was from 1 June 1999 until 30 April 2000, totaling **334 days**.

37 CFR § 1.776(d)(1)(iii)

The number of days equal to one-half the number of days remaining in the period defined by 35 U.S.C. § 156(g)(2)(B)(i) above after that period is reduced in accordance with 37 CFR § 1.776(d)(1) (i) and (ii) above is **958 days**, ignoring half days. [=1/2(2250-0-334)]

37 CFR § 1.776(d)(2)

The number of days as determined by d(1) above was added to the original term of U.S. Patent No. 4,600,706, shortened by any terminal disclaimer, and calculated to be **NOVEMBER 2, 2014**. [10.0 years 350 days from November 17, 2003]

37 CFR § 1.776(d)(3)

Fourteen (14) years from the date regulations were resolved and commercial marketing was permitted, April 13, 2003, is **APRIL 13, 2017**.

37 CFR § 1.776(d)(4)

The earlier date calculated by sections (d)(2) and (d)(3) above is be **NOVEMBER 2, 2014**.

37 CFR § 1.776(d)(5)(i)

U.S. Patent No. 4,600,706 issued after September 24, 1984, and, as such, the maximum allowable time period of five (5) years added to the expiration date, subject to a terminal disclaimer, is calculated to be **NOVEMBER 17, 2008.**

37 CFR § 1.776(d)(5)(ii)

The earlier date calculated by sections (d)(4) and (d)(5)(i) above is **NOVEMBER 17, 2008.**

The term for extension was calculated by taking the Regulatory Review time period, calculated under 35 U.S.C. § 156 (g)(2)(B), and reducing that number by the provisions set forth in 37 C.F.R. §1.776(d). The lesser of the maximum statutory allowable time period for extension (5 years) and the reduced Regulatory Review time period (14.9 years) determined the extension of patent term. Applicant asserts that U.S. Patent No. 4,600,706 should therefore expire on **NOVEMBER 17, 2008**, five years after the 4,600,706 patent was set to expire.

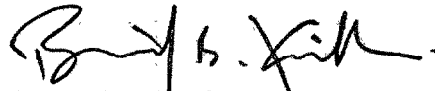
(13) Applicant acknowledges a duty to disclose to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services or the Secretary of Agriculture any information which is deemed material to the determination of entitlement to the extension sought.

(14) The prescribed fee of \$1,120.00, for receiving and acting upon the application for interim extension is included.

(15) Correspondence related to this application for extension of the patent term for U.S. Patent No. 4,600,706 should be addressed to Applicant's attorney Basil Krikelis, RatnerPrestia, Nemours Building, 1007 Orange St., Suite 1100, P.O. Box 1596, Wilmington Delaware 19899. Telephone 302-778-2500.

In accordance with 37 C.F.R. § 1.740(b), this original application is submitted with two additional copies (for a total of three copies).

Respectfully submitted,



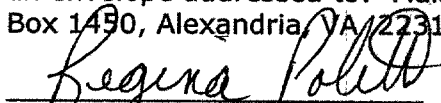
Basil S. Krikelis, Reg. No. 41,129  
Christian M. Bauer, Reg. No. 51,443  
Attorneys for Applicants

May 13, 2004

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Regina Poletti